

Appl. No.: 09/923,629
Group Art Unit: 1616
Applicants' Response to Paper No. 10

REMARKS

Claims 1-32 are currently pending in the present application.

In Paper No. 10, the Examiner withdraws the previous rejection of claims 10-12 and 32 under 35 U.S.C §103(a), over U.S. Pat. No. 5,703,252 of Hunt, *et al.* (hereinafter referred to as "Hunt '252"), in combination with U.S. Pat. No. 5,670,669 of Hunt, *et al.* (hereinafter referred to as "Hunt '669"). However, the Examiner maintains the rejection of claims 1-3, 6-9 and 13-31 as being unpatentable in view of Hunt '252 and Hunt '669, and makes the rejection final. In Paper No. 10, the Examiner also maintains the rejection of claims 4 and 5 under 35 U.S.C. §103(a), as being unpatentable over Hunt '252 and Hunt '669, further in view of U.S. Pat. No. 6,448,423 of Hernandez, *et al.* (hereinafter referred to as "Hernandez"), and makes the rejection final.

In Paper No. 10, the Examiner acknowledges Applicants' statement noting that the first transesterification step of the claimed process is performed "under mild transesterification conditions." (*See*, Paper No. 10, pp.2-3; *see also*, Applicants' Request for Reconsideration filed May 7, 2003 ("Applicants' Request for Reconsideration"), p. 3; *see also*, claim 1). However, the Examiner argues that "the instant claims lack definition of what 'mild transesterification conditions' are and, thus, are read to include any transesterification condition, including those taught by Hunt." (*See*, Paper No. 10, p. 2). The Examiner goes on to argue that while "the claims are read in light of the specification, limitations disclosed in the specification are not read into the claims." (*See, id.* at p.3). On these bases, the Examiner argues that the first transesterification step recited in the pending claims reads on conditions disclosed by the prior art and that the claimed process is obvious.

Applicants respectfully disagree with the Examiner's rejection and the arguments set forth in support thereof for the following reasons.

To begin with, while it is accurate that limitations disclosed in a specification are not to be read into the claims as claim limitations, it is incorrect to assert that a specification cannot be used to define a term or phrase explicitly set forth in a claim and discussed in the specification. The M.P.E.P. specifically states that, "... when the specification provides

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definitions for terms appearing in the claims, . . . the specification can be used in interpreting claim language." (See, M.P.E.P. 8th ed., §2111.01 citing *In re Vogel*, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970)).

The Examiner has argued that "mild transesterification conditions" are not defined in the claims. While the meaning of the phrase is not explicitly provided in claim 1, Applicants' Specification describes and explains the meaning of "mild transesterification conditions". As set forth in Applicants' Specification,

[t]he transesterification reaction takes place under mild conditions which may be established through the reaction temperatures or through the reaction time. Preferred conditions are temperatures T of 90 to 145°C, pressures p of 2 to 10 bar and more particularly 3 to 5 bar and reaction times of 2 to 20 minutes.
(See, Applicants' Spec., p. 6, lines 26-29).

Accordingly, Applicants submit that "mild transesterification conditions" are defined, by the Specification, as permitted. Moreover, Applicants submit that the "mild transesterification conditions" recited in the claims, as defined by the Specification, do not read on the prior art, for the reasons set forth in Applicants' Request for Reconsideration, as summarized below.

Applicants' claimed invention is directed to processes for producing sterols which comprise: (a) providing a fatty acid production-residue comprising sterol esters, free fatty acids, and partial glycerides; (b) removing the free fatty acids; (c) transesterifying the partial glycerides with a lower alcohol in the presence of a basic catalyst *under mild transesterification conditions* to form fatty acid alkyl esters and glycerol; (d) removing excess lower alcohol, the basic catalyst, the glycerol and the fatty acid alkyl esters, to form a bottom product comprising the sterol esters; and (e) transesterifying the sterol esters at a temperature of from 115°C to 145°C and a pressure of from 2 to 10 bar for a period of from 3 to 10 hours to form free sterols.

Neither Hunt '252, nor Hunt '669, nor a combination of the two references, teaches a process for producing sterols wherein a first transesterification is performed under the claimed mild conditions, as defined by the Specification, wherein very little sterol ester is converted to free sterol. Hunt '252 teaches the transesterification of the partial glycerides present in the starting material at temperatures of "between about 150°C and about 240°C and in

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reaction times of 10 minutes or more, *e.g.* about 1 to about 3 hours", under pressure. (*See*, Hunt '252, col. 5, lines 20-24). These conditions are not mild as claimed.

The differences between these relatively harsh transesterification conditions disclosed in the Hunt references and the "mild" transesterification conditions employed in the first transesterification according to Applicants' claimed invention are evidenced in three ways. First, the conditions disclosed in Hunt '252, as set forth above, are different than the conditions which are set forth in Applicants' Specification as being mild. Second, upon reviewing Hunt '252, one can see that the second transesterification, the transesterification of the sterol esters, is conducted under the same conditions as the first transesterification, namely temperatures of "between about 150°C and about 240°C and in reaction times of 10 minutes or more, *e.g.* about 1 to about 3 hours", under pressure. (*See*, Hunt '252, col. 6, lines 24-28). Hunt '252 discloses two transesterifications performed under identical conditions. Based upon the fact that the first transesterification is conducted under the same conditions disclosed for the transesterification of the sterol esters, it is clear that some sterol ester can be transesterified during the first transesterification disclosed in Hunt '252. Accordingly, it is clear that the first transesterification disclosed in Hunt '252 is different than the mild transesterification of Applicants' claimed invention. Third, Hunt '669 specifically discloses that in the pre-esterification/transesterification portion of the process disclosed therein that, "the sterol fatty acid ester is reacted to sterol and fatty acid methyl ester." (*See*, Hunt '669, col. 6, lines 58-62).

Accordingly, as the Hunt references fail to teach or suggest each and every element of the claimed invention, fail to motivate modification of their teachings such that one of ordinary skill in the art would arrive at the claimed invention, and fail to provide one of ordinary skill in the art with a reasonable expectation of success, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness based upon the Hunt references. Withdrawal of the rejection of claims 1-3, 6-9 and 13-31 under §103(a) is respectfully requested.

Applicants also submit that the Examiner has failed to establish a *prima facie* case of obviousness with respect to claims 4 and 5 based upon the Hunt references and Hernandez.

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As described above, the combined Hunt references fails to establish a *prima facie* case of obviousness. The Hernandez reference fails to remedy the deficiencies of the Hunt references. None of the references teaches the dual transesterification wherein the first transesterification is conducted under mild conditions.

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness based upon the combination of the Hunt references and the Hernandez reference. Withdrawal of the rejection of claims 4 and 5 under §103(a) is respectfully requested.

In view of the remarks set forth above, Applicants submit that all pending claims patentably distinguish over the prior art of record and known to Applicants, either alone or in combination. Accordingly, reconsideration, withdrawal of the rejections and a Notice of Allowance for all pending claims are respectfully requested.

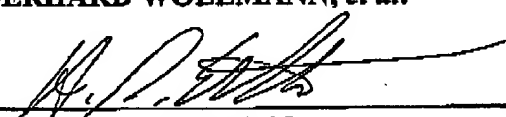
Respectfully submitted,
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